Medtronic Sofamor Danek
BUTTERFLY PLATE Fixation System
510(k) Summary
December 2001

K014267
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Submitter: Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132

JAN 2 5 2002

Contact Person: Richard Treharne

Trade Name: BUTTERFLY PLATE Fixation System

Classification Name: Spinal Intervertebral Body Fixation Orthosis, Class II

Predicate Device(s): The BUTTERFLY PLATE Fixation System is substantially equivalent to itself, the BUTTERFLY PLATE Fixation System, which was cleared in K010632 on May 31, 2001 and the Sofamor Danek Z-Plate Anterior Fixation System, which was cleared on May 19, 1993.

Device Description: The BUTTERFLY PLATE Fixation System construct consists of a plate fitted to match the antero-lateral vertebral bodies of the thoracic and lumbar spine. The plate is fastened to the bodies by either rigid bolts or variable-angle screws. The BUTTERFLY PLATE consists of a variety of shapes and sizes of plates, screws, bolts, and nuts, as well as ancillary products and instrument sets. The BUTTERFLY PLATE anterior implant components can be locked into a variety of configurations, with each construct being tailor-made for the individual case. The purpose of this submission is to add a cover plate to the system and to add a 6.5mm screw. The implant components are made of titanium alloy (Ti-6A1-4V) described by ASTM Standard F136 or ISO 5832-3. Stainless steel and titanium implant components must not be used together in a construct.

Intended Use: The BUTTERFLY™ PLATE Fixation System is intended for screw/bolt fixation/attachment to the anterolateral intervertebral bodies from T1 to L5 only. This system is to be used only on one side and placed in such a manner as to be as far away from blood vessels such as the aorta and nerve roots as possible.

When properly used, this system will provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

1. Degenerative Disc Disease (DDD as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Pseudoarthrosis.
3. Spondylolysis.
4. Spondylolisthesis.
5. Fracture.
6. Neoplastic disease.
7. Unsuccessful previous fusion surgery.
8. Lordotic deformities of the spine.
9. Idiopathic thoracolumbar or lumbar scoliosis.

10. Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele.
11. Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

Warning: This device is not approved for screw attachment to the posterior elements (pedicle) of the cervical, thoracic, or lumbar spine.

Functionality & Safety Testing: A Risk Analysis was performed on the BUTTERFLY PLATE and was included in this submission.

Conclusion: The subject components contained in this submission are substantially equivalent to the original BUTTERFLY PLATE Fixation System (K010632) and to the Sofamor Danek Z-Plate Anterior Fixation System (K922543).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K014267
Trade Name: Butterfly Plate Fixation System
Regulation Number: 888.3050 and 888.3070
Regulatory Name: Spinal interlaminal fixation orthosis and Pedicle Screw System
Regulatory Class: II
Product Code: KWP and MNH
Dated: December 21, 2001
Received: December 27, 2001

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

December 2001

510(k) Number (if known): K014267

Device Name: **BUTTERFLY PLATE FIXATION SYSTEM**

The BUTTERFLY™ PLATE Fixation System is intended for screw/bolt fixation/attachment to the anterolateral intervertebral bodies from T1 to L5 only. This system is to be used only on one side and placed in such a manner as to be as far away from blood vessels such as the aorta and nerve roots as possible. When properly used, this system will provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Evaluation (ODE)

Prescription Use X OR Over-the-counter Use _____

(Per 21 CFR 801.109)

(Optional 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorat
and Neurological Devices

510(k) Number K014267 003061